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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,498

Applicant(s)

LEE ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-33 is/are rejected.
- 7) ☒ Claim(s) 34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is responsive to the Amendment received on January 10, 2005 and the supplemental Amendment received on March 4, 2005.

Priority

Applicants are reminded that a National Phase application filed under 35 U.S.C. 171 may ***not*** claim benefit of the filing date of the international application of which it is the national stage ***since its filing date is the date of filing of that international application***. (See MPEP 1893.03(b)). Objection to the specification is maintained therefore.

Claim Objections

The objection of claim 5 for containing the word, "@" to mean the word, "at," made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The objection of claims 13 and 16 for minor issues noted in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

Claim Rejections - 35 USC § 112

The rejection of claims 1-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 4, 6, 7, 25 and 26 under 35 U.S.C. 102(b) as being anticipated by Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991), made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The rejection of claims 1, 4, and 8 under 35 U.S.C. 102(b) as being anticipated by Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991), made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The rejection of claims 29-31 and 33 under 35 U.S.C. 102(e) as being anticipated by Foote (U.S. Patent No. 5,944,971, issued August 31, 1999, priority September 29, 1995; cited in IDS received on June 14, 2002), made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

Claim Rejections - 35 USC § 103

The rejection of claims 3 and 8 under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991) and Cheng (U.S. Patent No. 5,512,462, issued April 30, 1996) made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

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The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991) and Cheng (U.S. Patent No. 5,512,462, issued April 30, 1996) as applied to claims 3 and 8 above, and further in view of Burckhardt (U.S. Patent No. 5,501,963, issued March 26, 1996) made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The rejection of claim 13-16, 18, and 27 under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999) made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The rejection of claims 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Little et al. (U.S. Patent No. 6,077,669, issued June 20, 2000, filed November 7, 1997) made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

The rejection of claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Danssaert et al. (U.S. Patent No. 5,525,300, issued June 11, 1996) made in the Office Action mailed on October 6, 2004 is withdrawn in view of the Amendment received on January 10, 2005.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 14-16, 18, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999) as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295).

Beutler et al. disclose a method of amplifying target nucleic acid, wherein said method involves the use of a buffer at pH of 8.8 (column 22, lines 26-42), said amplification reaction involving thermal cycling (column 22, lines 39-42).

With regard to claim 4, the buffer system employs 670 μ l (column 22, line 30) of 40 mM TrisHCl (column 21, line 20).

With regard to claim 5, while Beutler et al. are silent on at what temperature the TrisHCl buffer is employed, it is a common knowledge that such buffer is employed at 25°C, as evidenced by Heritz et al., wherein the artisans conduct PCR amplification employing, "Tris-HCl pH 8.5 at 25°C."

Additionally, with regard to claim 5, limitation drawn to molar concentration of Tris-HCl, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the teachings of Beutler et al., Kris et al., and Heritz et al., to conduct an empirical determination at arriving at optimal conditions required for amplifying a target nucleic acid via PCR.

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Absent secondary characteristic showing unexpected/superior result, it is well-within the purview of an ordinarily skilled artisan to empirically determine what parameters must be controlled for optimally amplifying a target nucleic acids. Such parameters comprises, the length and the identity of primers involved, the G-C content, the melting temperature of the target nucleic acid, magnesium concentrations, PCR buffer concentration. This is evident in the various PCR conditions employed by Beutler et al. (columns 23 and 24).

MPEP 2144.05(II)(A) discloses that, “differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical,” citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

With regard to claim 8, Beutler et al. also employ 80 mg/ml solution of bovine serum albumin (column 22, lines 31-32).

Beutler et al. do not explicitly disclose that the amplification was conducted in a disposable unit that comprises a thermally conducting layer and a facing layer having one or more reagent wells of up to 1000 microns in depth.

Beutler et al. do not explicitly discuss a kit comprising the reagents employed in their method further including the disposable unit discussed immediately above.

While the use of microtiter (in the form of 96 wells) plates is well-known in the art of amplification, and Beutler et al. do not explicitly state the use of such plates, Kris et al., state that 96, 384, 1536-well microtiter plates are well-known and commercially available (column 13, lines 26-30). While the microtiter plate of Kris et al. is not explicitly disclosed as thermally conducting, the make up of the plate would necessarily conduct heat for the thermocycling to

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occur. The limitation, "thermally conducting layer," based on a broadest reasonable interpretation, is determined to be a layer which passes heat. Whether the microtiter of Kris et al. is a good thermal conductor or not is not considered in this broad interpretation so long as the heat is passed through.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to conduct the amplification of Beutler et al. in multi-well microtiter plates of Kris et al. for the well-known benefit of amplifying a plurality of samples as well as packaging the reagents employed in the method of Beutler et al. with the microtiter plate of Kris et al. in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Therefore, the invention as claimed is obvious over the cited references.

Claims 1-5, 8-18, 21, 25-29, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Ronchi (U.S. Patent No. 6,372,484 B1, issued April 16, 2002, filed January 21, 2000, priority, January 25, 1999) as evidenced by as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295).

Beutler et al. disclose a method of amplifying target nucleic acid, wherein said method involves the use of a buffer at pH of 8.8 (column 22, lines 26-42), said amplification reaction involving thermal cycling (column 22, lines 39-42).

The buffer system employs 670 μ l (column 22, line 30) of 40 mM TrisHCl (column 21, line 20).

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While Beutler et al. are silent on at what temperature the TrisHCl buffer is employed, it is a common knowledge that such buffer is employed at 25°C, as evidenced by Heritz et al., wherein the artisans conduct PCR amplification employing, "Tris-HCl pH 8.5 at 25°C."

Beutler et al. also employ 80 mg/ml solution of bovine serum albumin (column 22, lines 31-32).

Beutler et al. do not explicitly disclose that the amplification was conducted in a disposable unit that comprises a thermally conducting layer and a facing layer having one or more reagent wells of up to 1000 microns in depth, wherein the thermally conducting metal layer of the disposable unit is metal, or aluminum, or involves heat-sealing the facing layer and thermally conducting layer.

Ronchi discloses an apparatus comprising a facing layer and a backing layer, a well formed therebetween (column 5, lines 36-38), wherein the facing layer is sealed (column 5, lines 48-49). The backing layer, in an alternative embodiment is made of polymeric materials, such as polypropylene, polyethylen, etc. (column 6, lines 22-27). Based on such disclosure, one of ordinary skill in the art would readily recognize that polystyrene would also be useful as a backing layer. The depth of the well formed between the facing layer and the backing layer is disclosed as being in the range of 0.25 mm to 1.27 mm, which is within 1000 microns (column 6, lines 40-44).

The reagent wells are disclosed as being filled via channel 36 (Figure 2), a single opening, through use of a pipett. The use of pipett fully meets the use of air pressure to force liquid into the device of Ronchi.

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With regard to claims 9 and 10, Ronchi discloses that aluminum blocks are used to sandwich the device on Ronchi for the benefit of even heat distribution (column 8, lines 64-66).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of teachings of Beutler et al. and Ronchi to arrive at the invention as claimed for the following reasons.

Conducting PCR in a closed environment as been well-established in the art of amplification for the benefit of sealing-in the vapor produced during thermal cycling events, precluding loss of sample volume and the possibility of contamination of PCR products via vaporization of the sample fluid during amplification cycle. Hence, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the PCR reaction involving the reaction conditions of Beutler et al. in a closed, sealed environment disclosed by Ronchi, for the advantage of conducting PCR in a sealed environment with a reasonable expectation of success.

While Ronchi does not disclose a backing layer that is made of metal, particularly, aluminum, *covered* with polymeric materials, *per se*, Ronchi sandwiches a sealed PCR chamber made of polymeric material between aluminum blocks, producing a functional identical structure. Ronchi, in doing this, explicitly discloses the advantage of using aluminum heat blocks, that is, even heat distribution (column 6, lines 61-65). Therefore, one of ordinary skill in the art would have been clearly motivated to produce a structure produced by Ronchi, but in an integrated way with a reasonable expectation of success.

With regard to kit claims 27 and 28, it would have been further obvious to package the reagents employed in the method of Beutler et al. with the device of Ronchi in view of the

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conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

With regard to claim 5, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the teachings of Beutler et al., Ronchi., and Heritz et al., to conduct an empirical determination at arriving at optimal conditions required for amplifying a target nucleic acid via PCR.

Absent secondary characteristic showing unexpected/superior result, it is well-within the purview of an ordinarily skilled artisan to empirically determine what parameters must be controlled for optimally amplifying a target nucleic acids. Such parameters comprises, the length and the identity of primers involved, the G-C content, the melting temperature of the target nucleic acid, magnesium concentrations, PCR buffer concentration. This is evident in the various PCR conditions employed by Beutler et al. (columns 23 and 24).

MPEP 2144.05(II)(A) discloses that, "differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical," citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

Therefore, the invention as claimed is obvious over the cited references.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999) as evidenced by Heritz et al. (Journal of Urology,

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1997, vol. 158, no. 6, pages 2291-2295), as applied to claims 1-5, 8, 14-16, 18, 25, and 26 above, and further in view of Moss et al. (U.S. Patent No. 5,386,021, issued January 31, 1995).

The teachings of Beutler et al., Kris et al., and Heritz et al. have already been discussed.

The above-artisans do not disclose a method of amplification involving detergent reagent, particularly in the concentration of 0.1% v/v.

Moss et al. disclose a method of amplifying a target nucleic acid via PCR, employing 0.1% Tween reagent (column 12, lines 12-17).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Beutler et al., Kris et al., and Heritz et al. with the teachings of Moss et al., combining commonly employed PCR reagents for the claimed method of amplification for the following reasons.

The art of PCR amplification is a well-established art (see filing date of Moss et al.).

MPEP 2144.05(II)(A) discloses that, “differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical,” citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

Hence, absent secondary characteristic showing unexpected/superior result, it is well-within the purview of an ordinarily skilled artisan to empirically determine what parameters must be controlled and reagents must be involved for optimally amplifying a target nucleic acids. Such parameters comprises, the length and the identity of primers involved, the G-C content, the melting temperature of the target nucleic acid, magnesium concentrations, detergent

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concentrations, PCR buffer concentration, rendering the invention as claimed obvious over the cited references.

Therefore, the invention as claimed is obvious over the cited references.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Ronchi (U.S. Patent No. 6,372,484 B1, issued April 16, 2002, filed January 21, 2000, priority, January 25, 1999) as evidenced by as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295), as applied to claims 1-5, 8-18, 21, 25-29, 32, and 33 above, and further in view of Moss et al. (U.S. Patent No. 5,386,021, issued January 31, 1995).

The teachings of Beutler et al., Kris et al., and Heritz et al. have already been discussed.

The above-artisans do not disclose a method of amplification involving detergent reagent, particularly in the concentration of 0.1% v/v.

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Beutler et al., Ronchi, and Heritz et al. with the teachings of Moss et al., combining commonly employed PCR reagents for the claimed method of amplification for the following reasons.

The art of PCR amplification is a well-established art (see filing date of Moss et al.).

MPEP 2144.05(II)(A) discloses that, "differences in concentrations or temperature will not support patentability of subject matter encompassed by prior art unless there is evidence

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indicating such concentration or temperature is critical,” citing *In re Aller*, F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995).

Hence, absent secondary characteristic showing unexpected/superior result, it is well-within the purview of an ordinarily skilled artisan to empirically determine what parameters must be controlled and reagents must be involved for optimally amplifying a target nucleic acids. Such parameters comprises, the length and the identity of primers involved, the G-C content, the melting temperature of the target nucleic acid, magnesium concentrations, detergent concentrations, PCR buffer concentration, rendering the invention as claimed obvious over the cited references.

Therefore, the invention as claimed is obvious over the cited references.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999) as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295) as applied to claims 1-4, 8, 14-16, 18, 25, and 26 above, and further in view of Little et al. (U.S. Patent No. 6,077,669, issued June 20, 2000, filed November 7, 1997).

The teachings of Beutler et al., Kris et al., and Heritz et al. have already been discussed above.

The above artisans do not explicitly teach that the reagents could be predosed in dried forms in at least one disposable unit having a plurality of wells.

Little et al. disclose a well-known method of providing reagents in a dried form in a disposable device (column 2, lines 30-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagents of Beutler et al., Kris et al., and Heritz et al. in their dried forms in the wells of a disposable device in order to provide devices comprising matched and preweighed reagents, for the obvious advantage of reducing contamination, and eliminating the time consuming steps of adding appropriate amounts of reagents for reactions to occur.

Therefore, the invention as claimed is obvious over the cited references.

Claims 19, 20, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Ronchi (U.S. Patent No. 6,372,484 B1, issued April 16, 2002, filed January 21, 2000, priority, January 25, 1999) as evidenced by as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295), as applied to claims 1-4, 8-18, 21, 25-29, 32, and 33 above, and further in view of Little et al. (U.S. Patent No. 6,077,669, issued June 20, 2000, filed November 7, 1997).

The teachings of Beutler et al., Ronchi, and Heritz et al. have already been discussed above.

The above artisans do not explicitly teach that the reagents could be predosed in dried forms in at least one disposable unit having a plurality of wells.

Little et al. disclose a well-known method of providing reagents in a dried form in a disposable device (column 2, lines 30-34).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagents of Beutler et al., Ronchi, and Heritz et al. in their dried forms in the wells of a disposable device in order to provide devices comprising matched and preweighed reagents, for the obvious advantage of reducing contamination, and eliminating the time consuming steps of adding appropriate amounts of reagents for reactions to occur.

Therefore, the invention as claimed is obvious over the cited references.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Ronchi (U.S. Patent No. 6,372,484 B1, issued April 16, 2002, filed January 21, 2000, priority, January 25, 1999) as evidenced by as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295), as applied to claims 1-4, 8-18, 21, 25-29, 32, and 33 above, and further in view of Danssaert et al. (U.S. Patent No. 5,525,300, issued June 11, 1996).

The teachings of Beutler et al., Ronchi and Heritz et al. have already been discussed above.

The above artisans do not explicitly teach the disposable unit being placed in an apparatus comprising at least two heating blocks.

Danssaert et al. disclose an apparatus comprising multiple heating blocks, said apparatus comprising: a) a plurality of reaction blocks (Figure 1, components 3, 17, 18, and 19), wherein at least one of the blocks is a heat reaction block and at least one of the blocks is a cold reaction block (Figure 3), wherein a reaction vessel (Figure 1, component 20) has a plurality of openings formed therein; b) a robotic arm which transfers the reaction vessels from one hot reaction block

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to one cold reaction block (Figure 1; column 1, lines 29-35; column 4, lines 35-42; column 5, lines 42-45); and c) a controller having a user interface for inputting temperature and sampling interval, the controller in communication with the blocks and robotic device (column 5, lines 25-42). The apparatus of Danssaert et al. conducts PCR (polymerase chain reaction) which is considered to be non-isothermal reaction (column 7). With regard to the apparatus of Danssaert et al., as well as most of the thermocycler, display the cycle times and their corresponding temperature at said cycle (Figure 1, component 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Beutler et al., Ronchi and Heritz et al. with the apparatus of Danssaert et al. for the advantage of determining the optical temperatures required in a PCR reaction (column 3, lines 5-8, Danssaert et al.).

Therefore, the invention as claimed is obvious over the cited references.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beutler et al. (U.S. Patent No. 5,234,811, issued August 10, 1993) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999) as evidenced by Heritz et al. (Journal of Urology, 1997, vol. 158, no. 6, pages 2291-2295) as applied to claims 1-4, 8, 14-16, 18, 25, and further in view of Danssaert et al. (U.S. Patent No. 5,525,300, issued June 11, 1996).

The teachings of Beutler et al., Kris et al., and Heritz et al. have already been discussed above.

The above artisans do not explicitly teach the disposable unit being placed in an apparatus comprising at least two heating blocks.

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Danssaert et al. disclose an apparatus comprising multiple heating blocks, said apparatus comprising: a) a plurality of reaction blocks (Figure 1, components 3, 17, 18, and 19), wherein at least one of the blocks is a heat reaction block and at least one of the blocks is a cold reaction block (Figure 3), wherein a reaction vessel (Figure 1, component 20) has a plurality of openings formed therein; b) a robotic arm which transfers the reaction vessels from one hot reaction block to one cold reaction block (Figure 1; column 1, lines 29-35; column 4, lines 35-42; column 5, lines 42-45); and c) a controller having a user interface for inputting temperature and sampling interval, the controller in communication with the blocks and robotic device (column 5, lines 25-42). The apparatus of Danssaert et al. conducts PCR (polymerase chain reaction) which is considered to be non-isothermal reaction (column 7). With regard to the apparatus of Danssaert et al., as well as most of the thermocycler, display the cycle times and their corresponding temperature at said cycle (Figure 1, component 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Beutler et al., Kris et al., and Heritz et al. with the apparatus of Danssaert et al. for the advantage of determining the optical temperatures required in a PCR reaction (column 3, lines 5-8, Danssaert et al.).

Therefore, the invention as claimed is obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

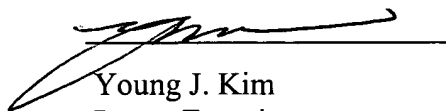
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The

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Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
5/27/2005

**YOUNG J. KIM
PATENT EXAMINER**

yjk